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Paper 25
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER, INC.,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Case IPR2018-00016
Patent 7,846,441 B1

Before ZHENYU YANG, CHRISTOPHER G. PAULRAJ, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

INTRODUCTION

Pfizer, Inc. filed a Petition (Paper 1 ("Pet.")), seeking an *inter partes* review of 1–14 of U.S. Patent No. 7,846,441 B1 ("the '441 patent"). Genentech, Inc. ("Patent Owner") filed a Preliminary response to the Petition (Paper 22 ("Prelim. Resp.")). As explained below, this is Pfizer's third Petition challenging claims 1–14 of the '441 patent.

For the following reasons, we exercise our discretion under 35 U.S.C. § 314(a), to deny this follow-on petition.

RELATED PROCEEDINGS

On January 20, 2017, Pfizer filed a petition, challenging claims 1–14 of the '441 patent. *Hospira, Inc. v. Genentech, Inc.*, IPR2017-00731 ("Pfizer IPR 1"), Papers 1, 13. On July 27, we denied institution in Pfizer IPR 1. IPR2017-00731, Paper 19. On August 25, Pfizer filed a request for reconsideration of the decision denying institution. IPR2017-00731, Paper 21. On October 26, we granted Pfizer's request for reconsideration, and instituted an *inter partes* review to determine whether claims 1–14 of the '441 patent would have been obvious over the combination of Baselga 1994[1] and Baselga 1996.[2] IPR2017-00731, Paper 21.

On March 21, 2017, Celltrion, Inc. challenged the same claims of the '441 patent as obvious under 35 U.S.C. § 103(a) over the combination of

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[1] Baselga et al., *Anti-HER2 Humanized Monoclonal Antibody (MAb) Alone and in Combination with Chemotherapy Against Human Breast Carcinoma Xenografts*, 13 Proc. AM. SOC. CLIN. ONCOL. 63 (Abstract 53) (1994) (Ex. 1006).

[2] Baselga et al., *Phase II Study of Weekly Intravenous Recombinant Humanized Anti-p185^{HER2} Monoclonal Antibody in Patients with HER2/neu-Overexpressing Metastatic Breast Cancer*, 14 J. CLIN. ONCOL. 737–44 (1996) (Ex. 1005).

Baselga 1996, Seidman 1996,[3] and the 1995 TAXOL PDR entry,[4] in view of the knowledge of a person of ordinary skill in the art. *Celltrion, Inc. v. Genentech, Inc.*, IPR2017-01121 ("Celltrion IPR"), Paper 1. On October 4, we instituted an *inter partes* review in Celltrion IPR. IPR2017-01121, Paper 9.

On September 7, Pfizer filed a second petition together with a motion to join Celltrion IPR. *Pfizer, Inc. v. Genentech, Inc.*, IPR2017-02063 ("Pfizer IPR 2"), Papers 2, 3. In a concurrently issued decision, we grant Pfizer's motion to join Celltrion IPR and institute an *inter partes* review in that case. IPR2017-02063, Paper 25 (PTAB February 21, 2018).

According to the parties, the '441 patent is also the subject of *Genentech, Inc. v. Pfizer, Inc.*, No. 1:17-cv-01672 (D. Del.) (Paper 7, 3); *Celltrion, Inc. v. Genentech, Inc.*, No. 3-18-cv-00274 (N.D. Cal.) (Paper 20, 3; Paper 21, 2); and *Genentech, Inc. v. Celltrion, Inc.*, No. 1-18-cv-00095 (D. Del.) (Paper 20, 3; Paper 21, 2).

DISCUSSION

Institution of *inter partes* review is discretionary. *See* 35 U.S.C. § 314(a); 37 C.F.R. § 42.108(a); *Harmonic Inc. v. Avid Tech, Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (explaining that under § 314(a), "the PTO is permitted, but never compelled, to institute an IPR proceeding"). When determining whether to exercise our discretion under § 314(a), we consider the following non-exhaustive factors:

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[3] Seidman et al., *Over-Expression and Clinical Taxane Sensitivity: A Multivariate Analysis in Patients with Metastatic Breast Cancer (MBC)*, 15 PROC. AM. SOC. CLIN. ONCOL. 104, Abstract 80 (Mar. 1996).
[4] Taxol® (Paclitaxel) for Injection Concentrate, PHYSICIANS' DESK REFERENCE, 682–85 (49th ed. 1995).

1. whether the same petitioner previously filed a petition directed to the same claims of the same patent;
2. whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it;
3. whether at the time of filing of the second petition the petitioner already received the patent owner's preliminary response to the first petition or received the Board's decision on whether to institute review in the first petition;
4. the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition;
5. whether the petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent;
6. the finite resources of the Board; and
7. the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review.

Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha, IPR2016-01357, Paper 19, 15–16 (PTAB Sept. 6, 2017) (precedential).

After weighing these factors, we agree with Patent Owner that it is appropriate to deny institution of this third petition by Petitioner challenging the '441 patent. *See* Prelim. Resp. 6–15. The first two factors, for example, weigh heavily in favor of denying institution. Petitioner has previously challenged the same claims of the '441 patent in Pfizer IPR 1 and Pfizer IPR 2. And at the time of filing the previous Pfizer IPRs, Petitioner knew of, or should have known of, the prior art asserted in this instant Petition.

Petitioner argues that claims 1–14 of the '441 patent would have been obvious over the combination of (1) Lottery[5] in view of Hayes[6] and/or Baselga '96, and Gelmon,[7] and (2) Baselga '96 in view of Baselga '94 and Gelmon. Pet. 6. In Pfizer IPR 1, Petitioner relied on both Baselga '96 and Baselga '94. *See* IPR2017-00731, Paper 1, 5. Although Gelmon was not of record of Pfizer IPR 1, Petitioner relied on this reference in an IPR concurrently filed with Pfizer IPR 1, challenging another patent in the same family of the '441 patent. *See Hospira, Inc. v. Genentech, Inc.*, IPR2017-00737, Paper 1, 4.

Hayes appears to be a new reference. It, however, was published in the same issue of the Journal of Clinical Oncology as Baselga '96. Thus, we agree with Patent Owner that Petitioner should have been aware of Hayes at the time of filing Pfizer IPR 1. *See* Prelim. Resp. 9.

Petitioner argues that Lottery was not previously identified because it is a newspaper article, "not the type of reference typically identified by a routine prior art search." Pet. 61. Patent Owner counters that Lottery is not analogous art because a newspaper article is different from "the nature of the art disclosed on the face of the '441 patent." Prelim. Resp. 8 (citing Pet. 61). We do not need resolve this issue because whether Petitioner should have been aware of Lottery is but one factor in our analysis. Under the totality of the circumstances in this case, it does not outweigh other factors in favor of denying institution.

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[5] A Lottery of Life, Death—and Hope, LA Times, published August 3, 1996 (Ex. 1008).
[6] Hayes, Editorial: Should We Treat HER, Too? 14 J. CLIN. ONCOL. 697–99 (1996) (Ex. 1009).
[7] Gelmon, et al., 14 J. CLIN. ONCOL. 1185–91 (1996) (Ex. 1016).

Indeed, other factors, such as factors 3 and 6, also weigh in favor of denying institution. At the time of filing the instant Petition, Petitioner already received Patent Owner's preliminary response and our initial decision on whether to institute review in Pfizer IPR 1. Petitioner contends that we should not deny this Petition because, it "could not have anticipated that Genentech would seek, and the Board would apply" certain claim construction in Pfizer IPR 1. Pet. 64. Given we have reconsidered that issue and have instituted an *inter partes* review in the rehearing decision in Pfizer IPR 1, the basis for this Petition appears moot. And instituting another trial to review the same claims already challenged in two other *inter partes* reviews (Pfizer IPR 1 and Celltrion IPR) is not the best allocation of the Board's finite resources.

The facts in this case are distinguishable from those in Pfizer IPR 2, in which we institute an *inter partes* review of claims 1–14 of the '441 patent. *See* IPR2017-02063, Paper 25. There, the petition is substantively identical to the one in Celltrion IPR. IPR2017-02063, Paper 3, 1. Petitioner seeks to join Celltrion IPR, and agrees that it will participate in the proceeding only in a secondary "understudy" role. *Id.* at 7–8. As a result, instituting an *inter partes* review in Pfizer IPR 2 does not result in undue prejudice against Patent Owner. Here, in contrast, there is no existing, instituted review based on the newly asserted prior art. Granting the Petition would require Patent Owner to respond separately to yet another challenge from the same Petitioner. This, would result in due prejudice against Patent Owner.

Thus, we exercise our discretion and deny the Petition.

ORDER

Accordingly, it is

ORDERED that Petitioner's request for *inter partes* review of claims 1–14 of the '441 patent is denied and no *inter partes* review is instituted.

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